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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,917	01/24/2001	Alain P. Vicari	SF0896K	5028

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/11/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.		Applicant(s)	
	09/768,917		VICARI ET AL	
	Examiner		Art Unit	
	Regina M. DeBerry		1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20 each in part, drawn to the method of making a pharmaceutical composition comprising use a chemokine capable of directing the migration of dendritic cell, wherein the activating agent is $\text{TNF}\alpha$, classified in class 514, subclass 2.
 - II. Claims 1-20 each in part, drawn to the method of making a pharmaceutical composition comprising a chemokine capable of directing the migration of dendritic cells, wherein the activating agent is RP-105, classified in class 514, subclass 3.
 - III. Claims 1-20 each in part, drawn to the method of making a pharmaceutical composition comprising a chemokine capable of directing the migration of dendritic cells, wherein the activating agent is anti-CD-40 antibody, classified in class 514, subclass 3.
 - IV. Claims 1-20 each in part, drawn to the method of making a pharmaceutical composition comprising a chemokine capable of directing the migration of dendritic cells, wherein the activating agent is nucleic acids containing unmethylated CpG motifs, classified in class 514, subclass 44.
 - V. Claims 1-20 each in part, drawn to the method of making a pharmaceutical composition comprising a chemokine capable of directing

the migration of dendritic cells, wherein the activating agent are ligands of toll-like receptors, classified in class 512, subclass 2.

- VI. Claims 21-36, drawn to a method of enhancing an immune response in a mammal comprising administering MCP-4, classified in class 514, subclass 2.
- VII. Claims 37-43, drawn to a fusion protein comprising MCP-4 and antigen, plasmid, viral vector, classified in class 435, subclass 69.1.
- VIII. Claims 44-59, drawn to a method of enhancing an immune response in a mammal comprising administering 6Ckine, classified in class 514, subclass 2.
- IX. Claims 60-66, drawn to a fusion protein comprising 6Ckine and antigen, plasmid, viral vector, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups VII and IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The products of Groups VII and IX are patentably distinct because they are composed of unrelated or diverse sequences, different coding regions and/or imparts structural and functional differences.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VI and VIII are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Inventions I-V each require making diverse pharmaceutical compositions, which is not required by any of the other groups. Inventions VI and VIII each require administration of a different protein to a mammal, which is not required by any of the other groups. Therefore, a search and examination of all methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions VII (product) and VI (process of use); IX (product) and VIII (process of use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups VII and IX can be used in processes to make recombinant proteins. In addition the method of enhancing an immune response in a mammal (Groups VI, VIII) can be practiced with another different product.

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2. Claims 2 and 9 are generic to a plurality of disclosed patentably distinct species (chemokine) comprising MCP-1, MCP-2, MCP-3, MCP-4, MIP-1 α , MIP-1 β , MIP-3 α , RANTES, SDF-1, Teck, DCtactin- β , 6Ckine/SLC, LEC, MDC, MIP-5 and MIP-1B. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Claim 5 is generic to a plurality of disclosed patentably distinct species (disease state) comprising bacterial infection, viral infection, fungal infection, parasitic infection and cancer. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. Claim 6 is generic to a plurality of disclosed patentably distinct species (disease state) comprising autoimmune disease, tissue rejection or an allergy. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Claims 7 is generic to a plurality of disclosed patentably distinct species (cancer) comprising melanoma, breast, pancreatic, colon, lung, glioma, hepatocellular, endometrial, gastric, intestinal, renal, prostate, thyroid, ovarian, testicular, liver, head and neck, colorectal, esophagus, stomach, eye, bladder, glioblastoma, and metastatic carcinomas. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. Claims 13, 29, 30, 40, 52, 53, and 63 are generic to a plurality of disclosed patentably distinct species (antigens) comprising bacterial, viral, and fungal. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Claims 14, 31, 32, 39, 54, 55 and 62 are generic to a plurality of disclosed patentably distinct species (tumor-associated antigen) comprising Melan-A, tyrosinase, p97, β -HCG, GaINAc, MAGE-1, MAGE-2, MAGE-3, MAGE-4, MAGE-12, MART-1, MUC1, MUC2, MUC3, MUC4, MUC18, CEA, DDC, melanoma antigen gp75, Hker 8, high molecular weight melanoma antigen, K19, Tyr1 and Tyr2, members of the pMel 17 gene family, c-Met, PSA, PSM, α -fetoprotein, thryroperoxidase, gp100, NY-ESO-1, telomerase and p53. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35

U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD

January 8, 2002

Elizabeth C. Kemmerer

ELIZABETH C. KEMMERER
PRIMARY EXAMINER